

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

**IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION**

MDL No. 2326

THIS DOCUMENT RELATES TO:

WAVE 7 CASES LISTED IN EXHIBIT A

**DEFENDANT BOSTON SCIENTIFIC'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS AND
TESTIMONY OF JIMMY W. MAYS, PH.D.**

Defendant Boston Scientific Corporation ("Boston Scientific"), pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby submits this Motion to Exclude the Testimony of Dr. Jimmy Mays and Memorandum in Support. Boston Scientific asks the Court to adopt its prior rulings relating to Dr. Mays's general causation opinions set forth in its order in *Frankum v. Boston Scientific*.¹ The following brief seeks to exclude the general causation opinions of Dr. Mays that the Court has previously excluded.

INTRODUCTION

Plaintiffs designated Dr. Jimmy Mays to offer general causation opinions regarding the alleged oxidative degradation of Boston Scientific's polypropylene mesh mid-urethral slings and pelvic organ prolapse kits.²

¹ A copy of the Daubert Order in *Frankum v. Boston Scientific* is attached as **Exhibit B**.

² A copy of Dr. Jimmy Mays Wave 4 report, incorporated by Plaintiffs in Wave 7, is attached as **Exhibit C**.

Boston Scientific notes that Dr. Mays does not include his previously excluded explant testing in his report for these cases on its face. Further, Dr. Mays did not conduct any new explant testing as part of this report. Despite not being included in his report, Dr. Mays does make reference to his and Dr. Gido's explant testing as a published article. Dr. Mays's explant testing remains unreliable and, further, is not disclosed in his expert report. Therefore, the Court should continue to preclude testimony regarding Dr. Mays's explant testing.

In support of his general causation opinions, Dr. Mays conducted thermogravimetric analysis ("TGA") on four commercial polypropylene pellets, seven pristine Boston Scientific pelvic mesh products, and one Pinnacle device from which he attempted to remove antioxidants. Dr. Mays's TGA is unreliable and should continue to be excluded for the following reasons: (1) his TGA admittedly has no correlation to performance of the polypropylene mesh *in vivo* and (2) Dr. Mays failed to use a control sample when attempting to remove the antioxidant from the Pinnacle sample.

Dr. Mays also includes in his report opinions regarding the Marlex HGX-030-01 polypropylene resin, the MSDS for that material, and the antioxidant package in that material. Any opinions or testimony regarding why Phillips Sumika Polypropylene Company began including the "Medical Application Caution" on the Marlex Polypropylene MSDS in 2004 is improper state of mind testimony based on speculation, not science.

Finally, Dr. Mays continues to offer opinions regarding Boston Scientific's state of mind as well as legal conclusions that are plainly inadmissible and should once again be excluded.

LEGAL STANDARD

The Federal Rules of Evidence and the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), require the trial judge, as a gatekeeper, to determine whether an expert's testimony is reliable and relevant. FED. R. EVID. 702; *Daubert*, 509 U.S. at 598; *Kumho Tire Co.*, 526 U.S. at 141.³ The proponent of the expert opinion bears the burden of establishing its admissibility. *See, e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Under Federal Rule of Evidence 702, an expert opinion must satisfy three prerequisites before being admitted. First, the expert must be adequately qualified by virtue of "knowledge, skill, experience, training or education," which is sufficiently related to the particular subjects at issue in the case. FED. R. EVID. 702; *see, e.g., Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998). The offered expert opinion must not go "beyond the expert[']s qualifications." *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011).

Second, the expert's opinion must assist "the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702(a). Admissibility under this prerequisite requires "an analysis of whether the opinion is relevant to the facts at issue." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999). If the opinion "does not relate to any issue in the case," it is inescapably "not relevant and ergo not helpful." *Daubert*, 509 U.S. at 591. The question is "one of 'fit,'" a quality that "is not always obvious." *Id.* This requirement is, however,

³ Federal law governs the admissibility of expert testimony in diversity actions. *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005). In multidistrict litigation, the law of the transferee circuit governs on federal law. *See, e.g., In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("In the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law.").

demanding. “[S]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.*

Further, the expert testimony must not be a mere regurgitation of factual information. *Hines*, No. 2:04-0690, 2011 WL 2680842, at *5. Expert testimony that “states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *U.S. v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). The expert must offer knowledge beyond the understanding of the average juror; testimony that will not assist the jury must be excluded. *Persinger v. Norfolk & W. Ry. Co.*, 920 F.2d 1185, 1188 (4th Cir. 1990) (affirming district court’s exclusion of expert opinion because it “did no more than state the obvious.”).

Third, the expert’s opinion and methodology must be reliable and the expert must reliably apply the methodology to the facts of the case. *Daubert*, 509 U.S. at 592-93. “A bold statement of the experts’ qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard.” *Doe 2 v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006). To be deemed reliable, the expert’s opinion “must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. Gen. Motors Corp.*, 190 F. 3d 244, 250 (4th Cir. 1999) (emphasis in original). Most importantly, the expert testimony must be trustworthy. *Westberry*, 178 F.3d at 260. Expert witnesses must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.

In determining the reliability of an expert opinion, *Daubert* provides the following factors for consideration: “(1) whether a theory or technique can be or has been tested; (2) whether it has

been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Smith & Nephew, Inc.*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592–94). These factors are “neither definitive, nor exhaustive.” *Id.* at 199–200. In light of the variability of the analysis, “the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho Tire Co.*, 526 U.S. at 152.

Expert testimony can be “both powerful and quite misleading.” *Daubert*, 509 U.S. at 595. Where the proponent fails to establish all of the prerequisites, the exclusion of expert testimony is within the court’s sound discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).

ARGUMENT

I. DR. MAYS’S EXPLAINT TESTING IS UNRELIABLE.

In his Report, Dr. Mays bases some of his opinions on testing that he and Dr. Guido conducted. *See* Report at 21–23, 25, citing n. 25 (A. Imel, T. Malmgren, M. Dadmun, S. Guido, and J. Mays, “*In-Vivo* Oxidative Degradation of Polypropylene Pelvic Mesh,” *Biomaterials*, 73, 131 (2015)). Dr. Mays confirmed at his deposition that there was no additional testing conducted for the article beyond the testing excluded by this Court. Mays Dep. 29:12–32:12 (Aug. 16, 2018).⁴ For instance, Dr. Mays states in his Report: “The oxidative degradation was accompanied by peeling, flaking, and cracking transverse to the fiber axis [see reference 25 and associated peer reviewed supplementary data available on-line]” *Id.* The MDL Court previously excluded all testimony regarding the testing performed by Dr. Mays and Dr. Guido as “unreliable because

⁴ A true and correct copy of excerpts of the August 16, 2018 deposition of Dr. Jimmy Mays is attached as **Exhibit D**.

they (1) failed to control for error or bias and (2) did not establish or adhere to testing protocols.” *Tyree*, 54 F.Supp.3d at 535-37. Moreover, the mere fact that the results of Dr. Mays’s and Dr. Guido’s testing were published does not necessarily mean that such testing is reliable or that its results are admissible under *Daubert*. As this Court has previously recognized, mere publication of unreliable testing does not make it reliable. *Mathison v. Bos. Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *26 (S.D.W. Va. May 6, 2015) (“[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability,” and is not dispositive.”). For all the reasons previously considered by the Court, Dr. Mays’s testing opinions should be excluded.

II. DR. MAYS’S TGA IS UNRELIABLE, IRRELEVANT, AND MUST BE EXCLUDED.

Dr. Mays performed TGA on seven Boston Scientific polypropylene mesh exemplars and four commercial polypropylene resins. Dr. Mays performed TGA to attempt and demonstrate the thermo-oxidative degradation profiles of the Boston Scientific pelvic mesh exemplars and the commercial polypropylene resins. This testing is also contained in the article cited to in footnote 25 of his Report. As previously held by this Court when considering the same testing, “‘Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.’ Here, Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the [mesh] degrades inside the human body.” *Frankum v. Boston Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *15 (S.D.W. Va. May 1, 2015) (excluding Dr. Mays’s testing) (internal citations omitted); *In Re: Boston Sci. Corp. Pelvic Repair Sys. Prods. Liab. Lit.*, MDL No. 2326, 2018 WL 2426132, at * 2 (S.D. W. Va. May 29, 2018) (“Dr. Mays failed to demonstrate a reliable connection between his TGA results and his conclusions about

polypropylene degradation in the human body.”). Any testimony regarding his TGA testing and results should be excluded.

III. DR. MAYS SHOULD NOT BE ALLOWED TO GIVE STATE OF MIND OPINIONS.

Dr. Mays should not be allowed to opine about the potential reasons behind Phillips Sumika and Chevron Phillips’ addition of the MSDS Medical Application Caution in 2004. Testimony regarding Chevron Phillips’ state of mind or intent should be excluded because opinions on these matters will not assist the jury. *See, e.g., In re Resulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (“Inferences about the intent or motives of parties or others lie outside the bounds of expert testimony...the question of intent is a classic jury question and not one for the experts.”) (internal quotations omitted). This is a direct attempt to opine concerning when Chevron Phillips knew certain information and Chevron Phillips’ intent in adding the medical application caution to the MSDS.

IV. DR. MAYS’S OPINIONS REGARDING BSC’S STATE OF MIND OR CORPORATE ETHICS SHOULD BE EXCLUDED AS IMPERMISSIBLE EXPERT TESTIMONY.

Dr. Mays attempts to opine on matters that go to the state of mind or corporate intent of BSC. This Court has repeatedly held that a defendant company’s “knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.” *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. June 4, 2013), on reconsideration in part (June 14, 2013).

In several places in his report, Dr. Mays attempts to offer opinions concerning BSC’s knowledge or corporate ethics in place of expert testimony. Dr. Mays opines that “BSC did not take into account polypropylene’s propensity for oxidation during design of its seven pelvic repair

meshes.” Report at p. 5. Because such knowledge, intent, and corporate ethics opinions are not proper expert testimony, they should be excluded. *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-0237, at *9 (“Ethicon’s knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.”).

CONCLUSION

For the foregoing reasons, Dr. Mays’s proposed testimony and opinions outlined above are inadmissible and should be excluded.

Dated: November 4, 2019

Respectfully submitted:

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Certificate of Service

I hereby certify that on November 4, 2019, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

Dated: November 4, 2019

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